Europäisches Patentamt
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Closure of the procedure in respect of application No. 05707853.7 - 2117 29.05.08

1. The procedure in respect of the above application is closed for the following reason:

✓ ADWI 11/19.02.08 The time limit under Rule 112(2) EPC has expired.
No request for a decision under Rule 112(2), or for further processing under Article 121 EPC or for re-establishment of rights under Article 122 EPC has been filed.

2. The EPASYS situation has been verified in respect of item 1:

DFIL: 27.01.05
NOAP: ////
RDEC: ////
RFPR: //
REES: ////

✗REFU✗3/ADWI 3 and DEAD 1 coded. Date of legal effect 15.01.08.

3. Position regarding fees:

FEFS01	002	00778850	18.12.06	EUR	720,00
DEST03	005	00556221	28.08.06	EUR	560,00
EXAM02	006	00556221	28.08.06	EUR	1 490,00
FFEE01	020	00556221	28.08.06	EUR	95,00
FEECODE	028	00174287	11.02.08	EUR	50,00
RFEE 03	033	00125295	12.01.07	EUR	400,00
RFEE 04	034	00171122	31.01.08	EUR	425,00
EXPT02	403	00556221	28.08.06	EUR	102,00
EXPT02	403	00023323	18.10.06	EUR	76,69
EXPT02	404	00556221	28.08.06	EUR	102,00
EXPT02	404	00023323	18.10.06	EUR	76,69
EXPT02	406	00556221	28.08.06	EUR	102,00
EXPT02	406	00023323	18.10.06	EUR	76,69
EXPT02	407	00556221	28.08.06	EUR	102,00
EXPT02	407	00023323	18.10.06	EUR	76,50
EXPT02	408	00556221	28.08.06	EUR	102,00
EXPT02	408	00023323	18.10.06	EUR	76,50
EXPT02	409	00556221	28.08.06	EUR	102,00
EXPT02	409	00023323	18.10.06	EUR	76,50

☐ 3.1 Form **2058A** submitted to 1st examiner (if applicable)

☐ 3.2 Refund(s) ordered:

☐ 75% Exam fee ☐ Other fees: _____

4. Mark "DEAD" on the paper file and:

☐ Check whether a divisional application is pending and if so attach the DEAD file to it.

☐ Any **models** still in the Office's possession were returned on _____
(for dealing with models, please refer to Fil d'Ariane).

☐ Submit it to 1st examiner if a request for feedback is present.

☐ Keep paper file in file store (separate place) until next action for file destruction.

29-05-2008
Date

Ullrich, Josef
Formalities Officer

To 1st examiner/Director for information : Ströter T room 3339

Europäisches Patentamt
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European Patent Office
80298 MUNICH
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Formalities Officer
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Date: 06-03-2008

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2117

Applicant/Proprietor: Nycomed GmbH

Revocation of the automatic debit order

Application No. 05707853.7

Your letter of 25/02/2008 revoking the automatic debit order for deposit account No. 28000022 was received on 26.02.08.

The automatic debit order for the above application thus ceased to be effective as from that date.

For the Examining Division

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Date: 19-02-2008

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2117

Applicant/Proprietor: Nycomed GmbH

Noting of loss of rights pursuant to Rule 112(1) EPC

The European patent application is deemed to be withdrawn under Article 94(4) EPC, because the invitation to file observations on the communication from the Examining Division dated 03.09.07 was not complied with.

Means of redress

Request for a decision (R. 112(2) EPC)
If the applicant considers that the finding of the European Patent Office is inaccurate, he may, within a (non-extendable) period of **two months** after notification of this communication, apply in writing for a decision on the matter. The application can only lead to the finding being reversed if this does not actually correspond to the factual or legal situation.

Further processing (Art. 121 EPC)
The legal consequence of the failure to observe the time limit shall be deemed not to have ensued if, within a (non-extendable) period of **two months** after notification of this communication, further processing is requested by payment of the fee prescribed under Article 2(12) of the Rules relating to Fees and the omitted act is completed (R. 135(1) EPC).

Important note to users of the automatic debiting procedure
The fee for further processing will be debited automatically on the day on which the above-mentioned omitted act is completed (see Arrangements for the automatic debiting procedure, Supplement to OJ EPO 10/2007).

For the Examining Division

Europäisches Patentamt • European Patent Office • Office européen des brevets •

Registered letter

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Europäisches Patentamt	European Patent Office	Office européen des brevets
Generaldirektion 2	Directorate General 2	Direction Générale 2

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Telephone numbers:

Primary Examiner (substantive examination) +49 89 2399-8088

Formalities Officer / Assistant (Formalities and other matters) +49 89 2399-8048

Application No.	Ref.	Date
05 707 853.7 - 2117	1278EPPCT01	03.09.2007
Applicant: Nycomed GmbH		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

Stroeter, Thomas
Primary Examiner
for the Examining Division

Enclosure(s): 3 page/s reasons (Form 2906)

Registered Letter
EPO Form 2001 07.02CSX

The examination is being carried out on the **following application documents**:

Description, Pages
1-10 as originally filed

Claims, Numbers
1-9 received on 26.07.2007 with letter of 23.07.2007

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1 The present claims 1-9 correspond to claims 1, 3 and 5-11 as originally filed wherein the subject-matter was restricted to zinc pantoprazole compounds in order to arrive at a unitary set of claims (Art. 82 EPC) which also fulfils the requirements of Art. 123(2) EPC.

2 The following documents are relevant for the examination of the present claims:
D1: WO 94/24867 A (SEPRACOR INC) 10 November 1994
D2: WO 99/27917 A (BYK GULDEN LOMBERG CHEM FAB) 10 June 1999
D3: WO 02/45686 A (BYK GULDEN LOMBERG CHEM FAB) 13 June 2002
D4: WO 2004/013126 A (HUMMEL ROLF-PETER et al) 12 February 2004
D5: WO 00/10995 A (BYK GULDEN LOMBERG CHEM FAB) 2 March 2000
D6: CN-A-1 369 491 (SHENYANG PHARMACY UNIV) 18 September 2002
D7: WO 03/061584 A (UNIV MISSOURI) 31 July 2003

3 The presently claimed zinc pantoprazole compounds, even the single R and S stereoisomers, were already disclosed in D6 and are therein described as anti-ulcer agents. Consequently present claims 1-9 are not novel (Art. 54 EPC).

4 In case that the presently claimed zinc salts of claims 1-3 or any other related subject-matter of claims 4-9 could indeed be seen as a novel contribution, the following considerations in view of the requirements of Art. 56 EPC have to be considered:

Bescheid/Protokoll (Anlage)	Communication/Minutes (Annex)	Notification/Procès-verbal (Annexe)
Datum Date Date 03.09.2007	Blatt Sheet Feuille 2	Anmelde-Nr.: Application No.: 05 707 853.7 Demande n°:

It is not apparent why the presently claimed Zn-salts should be considered to form part of an inventive solution to the problem of providing alternative pantoprazol salts useful as proton pump inhibitors (PPI): Na or Mg salts of racemic or optically active pantoprazole are disclosed in D1-D3 and D5 but it is also anticipated and suggested in the relevant prior art that metals such as Zn can be used as well in order to form other pharmacologically active salts, see document D7 (page 16, lines 17-18 in combination with page 33, lines 16-21). In the absence of any substantiated unexpected and advantageous properties of the present salts over the prior art salts no inventive contribution can be acknowledged for the provision of zinc pantoprazole salts as PPIs. Consequently present claims 1-9 are neither inventive (Art. 56 EPC).

NYCOMED

EPO - Munich
36
26. Juli 2007

Europäisches Patentamt

80298 München

Our Reference: 1278EPPCT01
RIP/PA - SR/
Your Reference:

Extension Phone/Fax
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DEKON.IPPA-DE@
nycomed.com

Constance
23.07.2007

EP Patent Application No 05707853.7-2117

Dear Mr. Ströter,

In response to the communication pursuant Art. 96(2), issued January 29th 2007 the applicant files a set of amended claims which are directed to the searched invention 3, zinc salts of pantoprazole and (S)-pantoprazole and which shall be subject of the further examination. A clear copy of amended claims is enclosed.

Following amendment have been made:

Claim 1 is limited to zinc salts.

Claims 2 and 4 are deleted.

Former claim 3 is limited to zinc (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide} and zinc bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, and the hydrates of these compounds. Further, the claim is made dependent to claim 1 and renumbered as amended claim 2.

The subsequent pending claims are renumbered and the dependencies are adapted accordingly.

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NYCOMED

With respect to the amendment of the description it is kindly requested to allow a postponement of this amendment after an agreement about patentable claims has been found.

The subject matter of the remaining inventions will be made part of divisional applications at a later point of time.

We would like to inform you that our company name has changed from ALTANA Pharma AG to Nycomed GmbH with effect from 14 June 2007. This name change has already been registered at the EPO patent register.

Yours faithfully,

i. V. Dr. Oliver Mechnich i. V. Dr. Stephan Riemann

Enclosures:
Originally filed claims with hand-written amendments
Clear copy of amended claims

Amended claims

1. Zinc salts of pantoprazole and (S)-pantoprazole, and hydrates thereof.

2. Zinc salts of pantoprazole and (S)-pantoprazole according to claim 1, wherein the zinc salt is zinc (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide} and zinc bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, and the hydrates of these compounds.

3. Zinc salts of pantoprazole or (S)-pantoprazole according to claim 1 or 2, with a particle size distribution of 99 % below 100 µm.

4. A medicament comprising a compound according to any of Claims 1 to 3 together with customary auxiliaries.

5. Medicament according to claim 4, wherein a single dose comprises from about 10 to about 100 mg of pantoprazole or (S)-pantoprazole, respectively.

6. Use of a compound according to any of Claims 1 to 3 for the manufacture of a medicament for treating gastrointestinal disorders.

7. Use of a (S)-pantoprazole compound according to any of Claims 1 to 3 for treating gastrointestinal disorders in patients who are slow metabolizers.

8. Use of a compound according to any of Claims 1 to 3 for the manufacture of a medicament for treating gastrointestinal disorders in patients who have a risk of drug interactions.

9. Use of a compound according to any of Claims 1 to 3 for the manufacture of a medicament for treating gastrointestinal disorders in patients who need an inhibition of acid secretion for an extended period of time.

Amended **Claims**

1. ~~Calcium, potassium,~~ zinc, ~~lithium and aluminium~~ salts of pantoprazole and (S)-pantoprazole, and hydrates thereof.

~~2. Calcium, potassium, zinc and aluminium salts of pantoprazole and (S)-pantoprazole, and hydrates thereof.~~

2 ~~8.~~ Zinc salts of pantoprazole and (S)-pantoprazole, wherein the zinc salt is ~~Calcium (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
zinc (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide},
~~aluminium (S)-tris{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
~~potassium (S)-{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
~~calcium bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
zinc bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide},
~~aluminium tris{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~
and
~~potassium {[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
and the hydrates of these compounds.

~~4. Lithium (S)-{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
~~and~~
~~lithium {[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}~~,
~~and the hydrates of these compounds~~.

3 ~~8.~~ Zinc salts of ~~A~~ pantoprazole or (S)-pantoprazole ~~salt~~ according to claim 1 or 2 ~~or 3 or 4, or a hydrate thereof~~, with a particle size distribution of 99 % below 100 µm.

4 ~~8.~~ Medicament comprising a compound according to any of Claims 1 to ~~5~~ 3 together with customary auxiliaries.

5 ~~7.~~ Medicament ~~comprising a compound~~ according to ~~any of~~ Claims ~~1 to 5 together with customary auxiliaries,~~ 4 or 3 wherein the single dose comprises from about 10 to about 100 mg of pantoprazole or (S)-pantoprazole, respectively.

6 ~~8.~~ Use of a compound according to any of Claims 1 to ~~5~~ 3 for treating gastrointestinal disorders.

7 ~~8~~. Use of a (S)-pantoprazole compound according to any of Claims 1 to ~~6~~ 3 for treating gastrointestinal disorders in patients who are slow metabolizers.

8 ~~10~~. Use of a compound according to any of Claims 1 to ~~9~~ 3 for treating gastrointestinal disorders in patients who have a risk of drug interactions.

9 ~~11~~. Use of a compound according to any of Claims 1 to ~~9~~ 3 for treating gastrointestinal disorders in patients who need an inhibition of acid secretion for an extended period of time.

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Nycomed GmbH
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Formalities Officer
Name: Ullrich
Tel.: 8048.

Date: 06.07.07

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2117

Applicant/Proprietor: Nycomed GmbH

Communication

concerning the registration of amendments relating to

☐ a transfer (Rules 20 and 61 EPC)

☑ entries pertaining to the applicant/the proprietor (Rule 92(1)(f) EPC)

As requested, the entries pertaining to the applicant of the above-mentioned European patent application / to the proprietor of the above-mentioned European patent have been amended to the following:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU MC NL
PL PT RO SE SI SK TR
Nycomed GmbH
Byk-Gulden-Strasse 2
78467 Konstanz/DE

The registration of the changes has taken effect on 28.06.07.

In the case of a published application/a patent, the change will be recorded in the Register of European Patents and published in the European Patent Bulletin (Section I.12/II.12).

Your attention is drawn to the fact that, in the case of the registration of a transfer, any automatic debit order only ceases to be effective from the date of its express revocation (cf. point 14(c) of the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 2/2002).

Transfer Service
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Europäisches Patentamt

80298 München

Our Reference: R61348 EP
RIP/PA - D. Wondrak
Your Reference: -

Phone/Fax
5224/5321
DEKON.IPPA-DE@
nycomed.com

UST

Konstanz
26.06.2007

Request for Change of Name
from ALTANA Pharma AG to Nycomed GmbH

Dear Madam or Sir,

As you can take from the enclosed copy of Commercial register HRB 701257 of Register Court Freiburg with effect of 14 June 2007 the name of our company has been changed from **ALTANA Pharma AG** to **Nycomed GmbH.** Address, phone and fax numbers remain unchanged. In our email addresses **@altanapharma.com** has to be replaced by **@nycomed.com.** Accordingly our common email address for patent purposes is **DEKON.IPPA-DE@nycomed.com.**

Enclosed you will find a list of our 193 European patent applications. We request to register the change of name for these patents as soon as possible. With separate post you will receive the request to register the change of name for our patents, for which the oppositons period is still running.

Your faithfully,

i. V. Dr. Oliver Mechnich i. V. Dr. Herbert Rupp

Enclosures:
List European patent applications (193)
Copy Excerpt Commercial Register HRB 701257

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Commerzbank AG Konstanz
Kto-Nr. 270 818 800, BLZ 690 400 45
Registergericht: Freiburg,
HRB-Nr. 701257
Vorsitzender des Aufsichtsrates:
Dr. Hans-Joachim Lohrisch
Vorstand:
Dipl-Kfm. Alfred Goll, Dr-Barthold Piening
Dr. Otto Schwarz, Dr. Anders Ullman

EP Patent Applications (193)

Status: 23.06.2007 / D. Wondrak

Our Reference	Application Number	Filing Date	Publication Number
1000EPPCT01	01909597.5-2101	10.01.2001	1250325
1002EPPCT01	01993583.2-2111	07.11.2001	1351887
1004EPPCT02	02751080.9-2103	27.06.2002	1463699
1008EPPCT01	01936419.9-2101	01.06.2001	1296956
1009EPPCT01	01990391.3-2117	06.11.2001	1335929
1010EPPCT01	01929463.6-1235	28.03.2001	1286999
1029EPPCT01	03704652.1-2123	19.02.2003	1478399
1034EPPCT01	01960370.3-2318	23.06.2001	1296633
1036EPDIV01	03020043.0-2114	08.12.1998	1371361
1043EPDIV01	06123558.6-1219	17.11.2001	1762249
1043EPPCT01	01997314.8-1219	17.11.2001	1339430
1046EPPCT01	01978447.9-2117	23.10.2001	1332143
1047EPPCT01	01990399.6-2101	08.11.2001	1337515
1051EPPCT01	01999360.9-1219	06.12.2001	1341528
1053EPPCT01	01991781.4-1219	05.12.2001	1341524
1055EPPCT01	01985365.4-1219	05.12.2001	1341523
1057EPPCT01	01999359.1-1219	06.12.2001	1341527
1058EPPCT02	02701277.2-2117	14.02.2002	1362044
1062EPPCT01	02740498.7-2117	24.04.2002	1385838
1063EPPCT01	02747291.9-2117	23.04.2002	1385848
1065EPPCT01	02724222.1-2103	12.03.2002	1370518
1085EPPCT01	02762419.6-2117	31.07.2002	1417208
1086EPPCT01	02764814.6-2119	31.07.2002	1419156
1090EPPCT01	02792742.5-2123	07.11.2002	1448202
1091EPPCT01	02777301.9-2107	10.10.2002	1435994
1094EPPCT01	03708130.4-2114	25.02.2003	1482938
1097EPPCT01	03744851.1-2117	25.03.2003	1490366
1099EPPCT01	02779565.7-1216	16.11.2002	1453493
1100EPPCT01	03735581.5-2117	07.06.2003	1515964
1103EPPCT01	03701506.2-2404	13.01.2003	1467770
1104EPPCT01	03704590.3-2117	12.02.2003	1476445
1105EPPCT01	03755048.0-2123	27.05.2003	1511516
1108EPPCT01	03711968.2-2123	11.03.2003	1487447
1109EPPCT01	03720509.3-2117	22.04.2003	1504003
1110EPPCT01	03744347.0-2123	11.03.2003	1490063
1112EPPCT01	04723609.6-2117	26.03.2004	1611150
1114EPPCT01	03766278.0-2101	24.07.2003	1534267
1115EPPCT01	03722539.8-2107	24.04.2003	1501605
1117EPPCT01	04718315.7-2117	08.03.2004	1606261
1118EPPCT01	03725140.2-1216	03.05.2003	1506016
1124EPPCT01	03755551.3-2123	29.08.2003	1545548
1125EPPCT01	03747866.6-2117	26.07.2003	1527066

Our Reference	Application Number	Filing Date	Publication Number
1132EPPCT01	03792307.5-2117	13.08.2003	1537086
1133EPPCT01	03792314.1-2117	13.08.2003	1581533
1134EPPCT01	04766387.7-2117	30.07.2004	1658270
1135EPPCT01	04766388.5-2117	30.07.2004	1658271
1136EPPCT01	05701549.7-2101	19.01.2005	1709007
1138EPPCT01	04716252.4-2117	02.03.2004	1601675
1141EPPCT01	04711371.7-2108	16.02.2004	1599175
1142EPPCT01	03779937.6-2117	15.11.2003	1565465
1143EPPCT01	04787257.7-1211	30.09.2004	1675853
1144EPPCT01	04820599.1-2117	30.09.2004	1670798
1145EPPCT01	03789344.3-2123	18.12.2003	1585516
1146EPPCT01	04725052.7-2117	01.04.2004	1613637
1148EPPCT01	03780056.2-2123	26.11.2003	1567140
1149EPPCT01	04726521.0-2114	08.04.2004	1615624
1150EPPCT01	03767663.2-2123	26.11.2003	1567139
1151EPPCT01	03782288.9-2117	03.12.2003	1578742
1152EPPCT01	03789113.2-2117	03.12.2003	1575941
1153EPPCT01	05743110.8-1219	04.05.2005	1746980
1154EPPCT01	04741525.2-2123	07.05.2004	1624869
1155EPPCT01	04741526.0-2123	07.05.2004	1624870
1156EPPCT01	03789217.1-2123	11.12.2003	1572217
1157EPPCT01	04701902.1-2123	14.01.2004	1587512
1158EPPCT01	04766017.0-2107	19.05.2004	1628682
1159EPPCT01	03785790.1-2117	11.12.2003	1575924
1160EPPCT01	04711620.7-2117	17.02.2004	1601663
1161EPPCT01	04711383.2-2117	16.02.2004	1599481
1164EPPCT01	04741597.1-2123	19.05.2004	1635844
1165EPPCT01	04741658.1-2107	26.05.2004	1644043
1167EPPCT01	04786242.0-2107	27.08.2004	1660132
1169EPPCT01	05716901.3-2107	03.03.2005	1740183
1170EPPCT01	03738637.2-2123	02.07.2003	1519734
1171EPPCT01	04723608.8-2123	26.03.2004	1610787
1172EPPCT01	04723611.2-2123	26.03.2004	1610788
1174EPPCT01	04817396.7-2107	29.10.2004	1682148
1175EPPCT01	04731016.4-2117	04.05.2004	1622905
1176EPPCT01	04741932.0-2117	30.06.2004	1641792
1178EPPCT01	04725396.8-2117	02.04.2004	1613626
1180EPPCT01	04741560.9-2117	13.05.2004	1631571
1182EPPCT01	04766789.4-2107	15.09.2004	1670481
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1199EPPCT01	04741761.3-2107	09.06.2004	1635845
1202EPORD01	06123855.6-2107	10.11.2006	
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1214EPPCT01	04766541.9-2123	19.08.2004	1658073
1215EPPCT01	05707837.0-2101	25.01.2005	1711498
1216EPPCT01	05708035.0-2101	17.02.2005	1718646
1217EPPCT01	06700346.7-2123	04.01.2006	
1218EPPCT01	04787165.2-2101	17.09.2004	1670795
1224EPPCT01	04804904.3-2107	17.12.2004	1696921
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1228EPPCT01	04787263.5-1211	30.09.2004	1675854
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1231EPPCT01	04766791.0-2107	15.09.2004	1670482
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1251EPPCT01	05769823.5-2401	28.07.2005	1789557
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Our Reference	Application Number	Filing Date	Publication Number
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B703EPPCT01	00962476.8-2101	12.09.2000	1216236
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Register B des Gerichts Freiburg i. Br.	Abteilung B Wiedergabe des aktuellen Registerinhalts Abruf vom 15.6.2007 6:51	Nummer der Firma: **HRB 701257**
-Amtlicher Ausdruck-	Seite 1 von 2	
Dieser Ausdruck wird nicht unterschrieben und gilt als beglaubigte Abschrift		

1. **Anzahl der bisherigen Eintragungen:**

   1

2. **a) Firma:**

   Nycomed GmbH

   b) Sitz, Niederlassung, Zweigniederlassungen:

   Konstanz

   c) Gegenstand des Unternehmens:

   Die Herstellung, die Erforschung und Entwicklung sowie der Vertrieb von und der Handel mit chemischen, pharmazeutischen, kosmetischen und dätetischen Erzeugnissen aller Art, die Errichtung, der Erwerb und der Betrieb von Fabriken und Anlagen für die Herstellung von chemischen, pharmazeutischen, kosmetischen und dätetischen Erzeugnissen und Substanzen, die Vergabe und die Verwertung von gewerblichen Schutzrechten und Lizenzen sowie jede sonstige gewerbliche Betätigung auf dem Gebiet der Industrie, des Gewerbes und des Handels im In- und Ausland.

3. **Grund- oder Stammkapital:**

   70.000.000,00 EUR

4. **a) Allgemeine Vertretungsregelung:**

   Ist nur ein Geschäftsführer bestellt, vertritt er allein. Sind mehrere Geschäftsführer bestellt, vertreten zwei gemeinsam oder ein Geschäftsführer mit einem Prokuristen. Die Geschäftsführer können von den Beschränkungen des § 181 BGB allgemein befreit werden.

   b) Vorstand, Leitungsorgan, geschäftsführende Direktoren, persönlich haftende Gesellschafter, Geschäftsführer, Vertretungsberechtigte und besondere Vertretungsbefugnis:

   Geschäftsführer: Goll, Alfred H., Allensbach, *17.10.1956
   Geschäftsführer: Dr. Piening, Barthold, Allensbach, *19.11.1958
   Geschäftsführer: Dr. Schwarz, Otto A., Thalwil (Schweiz), *13.10.1955
   Geschäftsführer: Dr. Ullman, Anders, Zürich (Schweiz), *22.01.1956

5. **Prokura:**

   Gesamtprokura gemeinsam mit einem Geschäftsführer oder einem anderen Prokuristen:
   Dr. Bösch, Lothar, Allensbach, *22.07.1950
   Frey, Hubertus, Allensbach, *20.06.1954
   Dr. Germann, Paul-Georg, Mölln, *10.11.1961
   Dr. Götz, Josef, Radolfzell am Bodensee, *17.09.1951
   Hermann, Walter, Konstanz, *25.10.1957
   Jauch, Joachim, Konstanz, *02.09.1955
   Kanzelmeyer, Wolf-Christian, Allensbach, *13.04.1956
   Kollmann, Stefan, Meerbusch, *20.11.1956
   Dr. Kröger, Bernd, Konstanz, *17.06.1958
   Kuner, Michael Franz, Freiburg im Breisgau, *14.12.1958
   de Lavenne, Philippe, Kreuzlingen (Schweiz), *23.10.1956
   Leu, Fernando, Bottighofen (Schweiz), *18.03.1945
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Dr. Schilling, Ulrich, Konstanz, *11.09.1951
Schneider, Joachim, Konstanz, *29.01.1948
Dr. Wiartalla, Rainer, Gottmadingen, *24.11.1950
Dr. Zech, Karl, Konstanz, *24.02.1944

6. **a) Rechtsform, Beginn, Satzung oder Gesellschaftsvertrag:**

Gesellschaft mit beschränkter Haftung

Gesellschaftsvertrag vom 25.04.2007

b) Sonstige Rechtsverhältnisse:

Die Gesellschaft ist entstanden durch formwechselnde Umwandlung
der Aktiengesellschaft
"ALTANA Pharma AG", Konstanz (Amtsgericht Freiburg i.Br. HRB 381925)
gemäß § 190 ff. UmwG.

7. **a) Tag der letzten Eintragung:**

14.06.2007

Freiburg i. Br., 15.06.2007
Der Ausdruck bezeugt den Inhalt des
Handelsregisters
Kopf, Justizsekretärin z. A.
Urkundsbeamter der Geschäftsstelle

AMTSGERICHT FREIBURG I. BR.

NYCOMED

EPO - Munich
44
28. Juni 2007

S FREA

Europäisches Patentamt

80298 München

E.Bkp 1 UST

Our Reference: R61348 EP
RIP/PA - D. Wondrak
Your Reference: -

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5224/5321
DEKON.IPPA-DE@
nycomed.com

UST

Konstanz
26.06.2007

Request for Change of Name
from ALTANA Pharma AG to Nycomed GmbH

Dear Madam or Sir,

As you can take from the enclosed copy of Commercial register HRB 701257 of Register Court Freiburg with effect of 14 June 2007 the name of our company has been changed from **ALTANA Pharma AG to Nycomed GmbH.** Address, phone and fax numbers remain unchanged. In our email addresses **@altanapharma.com** has to be replaced by **@nycomed.com.** Accordingly our common email address for patent purposes is **DEKON.IPPA-DE@nycomed.com.**

Enclosed you will find a list of our 193 European patent applications. We request to register the change of name for these patents as soon as possible. With separate post you will receive the request to register the change of name for our patents, for which the oppositons period is still running.

Your faithfully,

i. V. Dr. Oliver Mechnich i. V. Dr. Herbert Rupp

Enclosures:
List European patent applications (193)
Copy Excerpt Commercial Register HRB 701257

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Riemann, Stephan
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ALLEMAGNE

Formalities Officer
Name: Ullrich
Tel.: 8048

Date 08.06.07

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2117

Applicant/Proprietor
Altana Pharma AG

Extension of time limit pursuant to Rule 84 EPC

Examination procedure

With reference to your request, the time limit for replying to the communication dated 29.01.07 has been extended

by 2 months

to a total of 6 months

from the date of notification of the above-mentioned communication.

Please note: To the extent that your request exceeded the above extension, your request has been refused.

Note:
The granting of extensions to time limits is governed by the implementing Regulations to the EPC and the Guidelines for Examination in the EPO, part E-VIII, 1.6.

If no reply to the communication is received in due time, the European patent application will be deemed to be withdrawn (Article 96(3) EPC).

Examining Division

Europäisches Patentamt • European Patent Office • Office européen des brevets

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EINSCHREIBEN

Europäisches Patentamt

80298 München

EPO - Munich
22
25. Mai 2007

Our Reference: 1278EPPCT01
RIP/PA - SR/zi

Your Reference:

Extension Phone/Fax
5171/5321
DEKON.IPPA-DE@
altanapharma.com

Constance
23.05.2007

EP Patent Application No 05707853.7-2107
Request for extension of time limit
On your communication pursuant to Article 96(2) EPC dated 29.01.2007

Dear Madam or Sir,

We kindly ask you for an extension of two months of the time limit for filing our observations to the above-mentioned communication.

Additionally, we kindly ask you to send us a short confirmation, whether the extension of the time limit is granted.

With effect of 01 January 2007 ALTANA Pharma AG is a company of the Nycomed group. About a change-over of our current company name which is planned for later this year you will be informed in due time.

Yours faithfully,

i. V. Dr. Herbert Rupp i. V. Dr. Stephan Riemann

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IBAN: DE23 6904 0045 0270 8188 00
Country Court: Freiburg,
Commercial Register HRB 381925
Chairman Supervisory Board:
Dr. Hans-Joachim Lohrisch
Management Board:
Dipl-Kfm. Alfred Goll, Dr. Barthold Piening
Dr. Otto Schwarz, Dr. Anders Ullman

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Generaldirektion 2 | Directorate General 2 | Direction Générale 2

Telephone numbers:
Primary Examiner (substantive examination) +49 89 2399-8088
Formalities Officer / Assistant (Formalities and other matters) +49 89 2399-0

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78403 Konstanz
ALLEMAGNE

Application No.	Ref.	Date
05 707 853.7 - 2117	1278EPPCT01	29.01.2007
Applicant: Altana Pharma AG		

Communication pursuant to Article 96(2) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(1) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 78(2) and 83(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (Rule 36(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Article 96(3) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

Stroeter, Thomas
Primary Examiner
for the Examining Division

Enclosure(s): 3 page/s reasons (Form 2906)

Registered Letter
EPO Form 2001 07.02CSX

The examination is being carried out on the **following application documents**:

Description, Pages
1-10 as originally filed

Claims, Numbers
1-10 received on 29.09.2006 with letter of 26.09.2006

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1 An European Search Report under Rule 112 EPC was obtained for invention 3 as defined in the International Search Report and the European Search Report.

The Applicant is informed that **one** of the searched inventions 1 and 3 could be subject to examination. Since it is not clear on which invention or group of inventions the further prosecution of the application should be based, no further examination can be carried out. The applicant is asked to state upon which invention further prosecution of the application should be based and to limit the application accordingly. The other inventions are to be excised from the claims, description and drawings if any.

The subject-matter to be excised may be made the subject of one or more divisional applications. The divisional applications must be filed directly at the European Patent Office in Munich or its branch at The Hague and in the language of the proceedings relating to the present application, cf. Article 76(1) and Rule 4 EPC. The time limit for filing divisional applications (Rule 25(1) EPC) must be observed.

2 If the further prosecution of the application should be based on invention 1, then the Applicant is informed that:

2.1 An International Preliminary Examination Report has already been drawn up for said invention 1 in accordance with the PCT. The deficiencies mentioned in that report under item V.4 give rise to objections under the corresponding provisions of Art. 56 EPC.

2.2 Since the claimed priority dates for both the presently claimed subject-matter of invention 1 and the document D4 appear to be valid, it is to be noted that D4 is relevant to the question of novelty according to Art. 54(3) EPC: D4 mentions Ca-salts of pantoprazol rendering the Ca salts of claims 1-3 not novel.

3 The present application contains the following groups of independent claims:
(1) 4 compound claims 1-4
(2) 2 pharmaceutical composition/medicament claims 5 and 6
(3) 4 use claims 7-10

Under Article 84 in combination with Rule 29(2) EPC an application may contain more than one independent claim in a particular category only if the subject matter claimed falls within one or more of the exceptional situations set out in paragraphs (a), (b) or (c) of Rule 29(2) EPC which, however, is not the case for the present application.

Although said claims are drafted as separate independent claims, each group of claims of a certain category appears to relate effectively to the same subject-matter and the claims therein differ from each other only with regard to the manner in which the subject-matter for which protection is sought is defined and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claim makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, said claims do not meet the requirements of Art. 84 EPC.

A possible solution would be e.g.: Claims 2-4 could be made dependent on claim 1, claim 5 could be made dependent on claim 6 and claims 8-10 could be made dependent on claim 1.

4 The Applicants' attention is drawn to the important fact, that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC). The content of the description has to be adapted to the amendments of the claims.

Additionally, one set indicating the amendments in hand-writing on a copy of the relevant parts of the application as filed should be provided. The Applicant, furthermore, should clearly indicate those passages of the application as filed which serve as a basis for said amendments (Guidelines E-II, 1). When filing new claims the complete set of claims should be filed rather than single amended sheets.

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Zweigstelle in Den Haag Recherchenabteilung	Branch at The Hague Search division	Département à La Haye Division de la recherche

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COPY

Datum/Date
25. 01. 2007

Zeichen/Ref./Réf.	Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./Brevet n°.
1278EPPCT01	05707853.7 - -

Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire
Altana Pharma AG

COMMUNICATION

The European Patent Office herewith transmits

- ☐ the European search report
- ☐ the declaration under Rule 45 EPC
- ☐ the partial European search report under Rule 45 EPC
- ☒ the European search report under Rule 112 EPC

relating to the above-mentioned European patent application. Copies of the documents cited in the search report are enclosed.

The following specifications given by the applicant have been approved by the Search Division :

☐ Abstract ☐ Title ☐ Figure

☐ The abstract was modified by the Search Division and the definitive text is attached to this communication.

☐ The following figure will be published with the abstract, since the Search Division considers that it better characterises the invention than the one indicated by the applicant.

Figure:

☐ Additional copy(copies) of the documents cited in the European search report.

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REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

European Patent Office

EUROPEAN SEARCH REPORT

under Rule 112 EPC

Application Number
EP 05 70 7853

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
	On request of the applicant the present search report has been drawn up for a part of the subject-matter claimed in claims 1-10 relating to inventions 1 and 3.		INV. A61K31/4439 A61P1/04 C07D401/12
X,D	WO 94/24867 A (SEPRACOR INC) 10 November 1994 (1994-11-10) Claims, examples	1-10	
D,X	WO 99/27917 A (BYK GULDEN LOMBERG CHEM FAB ; NEY HARTMUT (DE); DIETRICH RANGO (DE)) 10 June 1999 (1999-06-10) * abstract; claim 5 *	1-10	
D,X	WO 02/45686 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); DIETRICH RANGO (DE)) 13 June 2002 (2002-06-13) * page 5, paragraph 3 *	1-10	
D,P, X	WO 2004/013126 A (HUMMEL ROLF-PETER ; HANAUER GUIDO (DE); KOHL BERNHARD (DE); MUELLER BE) 12 February 2004 (2004-02-12) * page 3, line 6 *	1,2	TECHNICAL FIELDS SEARCHED (IPC) A61K A61P C07D
A,D	WO 00/10995 A (BYK GULDEN LOMBERG CHEM FAB ; KOHL BERNHARD (DE)) 2 March 2000 (2000-03-02) * claims 1-3 *	1-10	
X	CN 1 369 491 A (SHENYANG PHARMACY UNIV) 18 September 2002 (2002-09-18) * abstract; claims 1-8 *	1-10	
A	WO 03/061584 A (UNIV MISSOURI) 31 July 2003 (2003-07-31) * page 33, line 16 - line 21 *	1-10	

Place of search	Date of completion of the search	Examiner
Munich	12 January 2007	Stroeter, Thomas

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C64)

European Patent Office

Application Number
EP 05 70 7853

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☒ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

1-10 (in part)

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

European Patent Office

LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 05 70 7853

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-10 (in part)

   Calcium salts of pantoprazole and (S)-pantoprazole and hydrates thereof and subject-matter related to these compounds.

   ---

2. claims: 1-10 (in part)

   Potassium salts of pantoprazole and (S)-pantoprazole and hydrates thereof and subject-matter related to these compounds.

   ---

3. claims: 1-10 (in part)

   ZInc salts of pantoprazole and (S)-pantoprazole and hydrates thereof and subject-matter related to these compounds.

   ---

4. claims: 1-10 (in part)

   Lithium salts of pantoprazole and (S)-pantoprazole and hydrates thereof and subject-matter related to these compounds.

   ---

5. claims: 1-10 (in part)

   Aluminium salts of pantoprazole and (S)-pantoprazole and hydrates thereof and subject-matter related to these compounds.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 70 7853

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

12-01-2007

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9424867 A	10-11-1994	AU 6713194 A	21-11-1994
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		CN 1479611 A	03-03-2004
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		EA 4431 B1	29-04-2004
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		ES 2178896 T3	01-01-2003
		HK 1037616 A1	25-10-2002
		HR 20010117 A2	28-02-2002
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		NO 20010718 A	12-02-2001
		NZ 509761 A	29-08-2003
		PL 345993 A1	14-01-2002

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 70 7853

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

12-01-2007

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0010995 A		PT 1105386 T	29-11-2002
		SK 2362001 A3	11-09-2001
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		MX PA04006912 A	15-10-2004

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

CONFIRMATION COPY

Pharma

ALTANA

EPO - Munich
42
12. Dez. 2006

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Europäisches Patentamt

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Your Reference

Our Reference
1278EPPCT01

In advance by FAX: 089 2399 4465

Constance
07.12.2006

EP Patent Application No 05707853.7-2107

Dear Madam or Sir,

This letter is in response to the communication under Rule 112 of the European Patent Office, dated November 8th 2006 with respect to the pending European patent application 05707853.7-2107.

The applicant requests an additional European Search Report with respect to the invention numbered as invention 3 in the International Search Report (zinc salts of pantoprazole and (-)-pantoprazole and hydrates thereof). The corresponding fee should be charged to applicants account 2800 0022.

As soon as the applicant receives the additional European Search Report amended claims will be filed which will serve as the basis for the subsequent examination.

Yours faithfully,
ALTANA Pharma AG

i. V. Dr. Oliver Mechnich i. V. Dr. Stephan Riemann

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Europäisches Patentamt

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In advance by FAX: 089 2399 4465

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Your Reference

Our Reference
1278EPPCT01

Constance
07.12.2006

EP Patent Application No 05707853.7-2107

Dear Madam or Sir,

This letter is in response to the communication under Rule 112 of the European Patent Office, dated November 8th 2006 with respect to the pending European patent application 05707853.7-2107.

The applicant requests an additional European Search Report with respect to the invention numbered as invention 3 in the International Search Report (zinc salts of pantoprazole and (-)-pantoprazole and hydrates thereof). The corresponding fee should be charged to applicants account 2800 0022.

As soon as the applicant receives the additional European Search Report amended claims will be filed which will serve as the basis for the subsequent examination.

Yours faithfully,
ALTANA Pharma AG

i. V. Dr. Oliver Mechnich i. V. Dr. Stephan Riemann

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Telephone numbers:

Primary Examiner (substantive examination)	+49 89 2399-8088
Formalities Officer / Assistant (Formalities and other matters)	+49 89 2399-0

Application No.	Ref.	Date
05 707 853.7 - 2117	1278EPPCT01	08.11.2006
Applicant: Altana Pharma AG		

Communication under Rule 112 EPC

In respect of the above identified European Patent Application, only a partial International Search Report has been drawn up by the EPO acting as International Searching Authority, because of an objection by the International Searching Authority that the application relates to more than one invention (c.f Article 17, paragraph (3) (a) PCT).

In the procedure before the European Patent Office as a(n) designated/elected Office, the Examining Division agrees with the objection put forward by the International Searching Authority as to lack of unity, the reasons for the objection being indicated in the annex (Form 2906).

In accordance with Rule 112 EPC, the applicant can now obtain a European search report in respect of those parts of the application which have not been searched if a European search fee is paid for each invention involved (or group of inventions within the meaning of Rule 46 EPC - hereinafter referred to as the "invention") within a period

of one month

from the date of notification of the present communication.

After the further search report(s) has (have) been drawn up, the applicant will be required to indicate on which invention he wishes further prosecution of the application to be based, and to limit the application accordingly.

If the applicant does not elect to have a search report drawn up on the other invention/s/ (Rule 46 EPC), the application will be prosecuted on the basis of the invention in respect of which a search has already been carried out, in other words the invention first mentioned in the claims (Art. 94, Rule 51 EPC). The applicant should therefore in this case limit the application to the invention searched and excise those parts of the application relating to the other invention/s/.

The subject-matter to be excised may be made the subject of one or more divisional applications. The divisional applications must be filed directly at the European Patent Office in Munich or its branch at The Hague and in the original language of the proceedings relating to the present application, cf. Article 76(1) and Rule 4 EPC.

Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 01/2005.

Registered Letter
EPO Form 2002 03.00CSX

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Stroeter, Thomas
Primary Examiner
for the Examining Division

Enclosure(s): 3 page/s reasons (Form 2906)

Registered Letter
EPO Form 2002 03.00CSX

The examination is being carried out on the **following application documents**:

Description, Pages
1-10 as originally filed

Claims, Numbers
1-10 received on 29.09.2006 with letter of 26.09.2006

---

1 The Examining Division agrees with the objection put forward by the International Preliminary Examination Authority as to lack of unity. The Applicant is hereby informed that a European Search Report can be obtained in respect of those parts of the present application which have not yet been searched, i.e. inventions 2-5 as defined in the International Search Report, if the required search fees are paid for these inventions.

2 The Applicant is informed that **one** of inventions 1 and inventions 2, 3, 4 or 5 (if paid) could be subject to examination. Since it is not clear on which invention or group of inventions the further prosecution of the application should be based, no further examination can be carried out. The applicant is asked to state upon which invention further prosecution of the application should be based and to limit the application accordingly. The other inventions are to be excised from the claims, description and drawings if any.

The subject-matter to be excised may be made the subject of one or more divisional applications. The divisional applications must be filed directly at the European Patent Office in Munich or its branch at The Hague and in the language of the proceedings relating to the present application, cf. Article 76(1) and Rule 4 EPC. The time limit for filing divisional applications (Rule 25(1) EPC) must be observed.

3 If the further prosecution of the application should be based on invention 1, then the Applicant is informed that:

3.1 An International Preliminary Examination Report has already been drawn up for said invention 1 in accordance with the PCT. The deficiencies mentioned in that report under item V.4 give rise to objections under the corresponding provisions of Art. 56 EPC.

3.2 Since the claimed priority dates for both the presently claimed subject-matter of invention 1 and the document D4 appear to be valid, it is to be noted that D4 is relevant to the question of novelty according to Art. 54(3) EPC: D4 mentions Ca-salts of pantoprazol rendering the Ca salts of claims 1-3 not novel.

4 The present application contains the following groups of independent claims:
(1) 4 compound claims 1-4
(2) 2 pharmaceutical composition/medicament claims 5 and 6
(3) 4 use claims 7-10

Under Article 84 in combination with Rule 29(2) EPC an application may contain more than one independent claim in a particular category only if the subject matter claimed falls within one or more of the exceptional situations set out in paragraphs (a), (b) or (c) of Rule 29(2) EPC which, however, is not the case for the present application.

Although said claims are drafted as separate independent claims, each group of claims of a certain category appears to relate effectively to the same subject-matter and the claims therein differ from each other only with regard to the manner in which the subject-matter for which protection is sought is defined and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claim makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, said claims do not meet the requirements of Art. 84 EPC.

A possible solution would be e.g.: Claims 2-4 could be made dependent on claim 1,

claim 5 could be made dependent on claim 6 and claims 8-10 could be made dependent on claim 1.

5 The Applicants' attention is drawn to the important fact, that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC). The content of the description has to be adapted to the amendments of the claims.

Additionally, one set indicating the amendments in hand-writing on a copy of the relevant parts of the application as filed should be provided. The Applicant, furthermore, should clearly indicate those passages of the application as filed which serve as a basis for said amendments (Guidelines E-II, 1). When filing new claims the complete set of claims should be filed rather than single amended sheets.

Pharma

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28
29. Sep. 2006

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Your Reference

Our Reference
1278EPPCT01

Constance
26.09.2006

EP Patent Application No 05707853.7-2107
Communication pursuant to Rules 109 and 110 EPC dated 13.09.2006

Dear Madam or Sir,

We refer to the above-mentioned communication pursuant to Rules 109 and 110. Enclosed is a set of amended claims as basis for further prosecution of our EP patent application.

Yours faithfully,
ALTANA Pharma AG

i. V. Dr. Herbert Rupp i. V. Dr. Stephan Riemann

Enclosures:
1 set of amended claims
1 acknowledgement receipt

Claims

1. Calcium, zinc, lithium, potassium and aluminium salts of pantoprazole and (S)-pantoprazole, and hydrates thereof.

2. Lithium (S)-{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, and lithium {[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide} and the hydrates of these compounds.

3. Calcium (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, zinc (S)-bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, aluminium (S)-tris{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methyl-sulphinyl]-1H-benzimidazolide}, potassium (S)-{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)-methylsulphinyl]-1H-benzimidazolide}, calcium bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)-methylsulphinyl]-1H-benzimidazolide}, zinc bis{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)-methylsulphinyl]-1H-benzimidazolide}, aluminium tris{[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide} and potassium {[5-(difluoromethoxy)]-2-[(3,4-dimethoxy-2-pyridinyl)methylsulphinyl]-1H-benzimidazolide}, and the hydrates of these compounds.

4. A pantoprazole or (S)-pantoprazole salt or a hydrate thereof according to claim 1 or 2 or 3 with a particle size distribution of 99 % below 100 µm.

5. Medicament comprising a compound according to any of Claims 1 to 4 together with customary auxiliaries.

6. Medicament comprising a compound according to any of Claims 1 to 4 together with customary auxiliaries, where the single dose comprises from about 10 to about 100 mg of pantoprazole or (S)-pantoprazole, respectively.

7. Use of a compound according to any of Claims 1 to 4 for the manufacture of a medicament for treating gastrointestinal disorders.

8. Use of a (S)-pantoprazole compound according to any of Claims 1 to 4 for the manufacture of a medicament for treating gastrointestinal disorders in patients who are slow metabolizers.

9. Use of a compound according to any of Claims 1 to 4 for the manufacture of a medicament for treating gastrointestinal disorders in patients who have a risk of drug interactions.

10. Use of a compound according to any of Claims 1 to 4 for the manufacture of a medicament for treating gastrointestinal disorders in patients who need an inhibition of acid secretion for an extended period of time.

P.B.5818 - Patentlaan 2
2280 HV Rijswijk (ZH)
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Europäisches Patentamt	European Patent Office	Office européen des brevets
Generaldirektion 1	Directorate General 1	Direction générale 1

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EPO Customer Services
Tel.: +31 (0)70 340 45 00

Date
20.09.06

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2107 PCT/EP2005050334

Applicant/Proprietor
Altana Pharma AG

Notification of European publication number and information on the application of Article 67(3) EPC

The provisional protection under Article 67(1) and (2) EPC in the individual contracting states becomes effective only when the conditions referred to in Article 67(3) EPC have been fulfilled (for further details, see information brochure of the European Patent Office "National Law relating to the EPC" and additional information in the Official Journal of the European Patent Office).

A request has been made for extension of the patent to: AL BA HR LV MK YU
See Official Journal 1-2/1994 for further information on provisional protection.

Pursuant to Article 158(1) EPC the publication under Article 21 PCT of an international application for which the European Patent Office is a designated Office takes the place of the publication of a European patent application.

The bibliographic data of the above-mentioned Euro-PCT application will be published on 18.10.06 in Section I.1 of the European Patent Bulletin. The European publication number is 1711179.

In all future communications to the European Patent Office, please quote the application number plus Directorate number.

Receiving Section

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Europäisches Patentamt	European Patent Office	Office européen des brevets
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Date
13-09-2006

Reference	Application No./Patent No.
1278EPPCT01	05707853.7 - 2107 PCT/EP2005050334
Applicant/Proprietor: Altana Pharma AG	

Communication pursuant to Rules 109 and 110 EPC

(1) Amendment of application documents, especially the claims (R. 109 EPC)

The above mentioned international (Euro-PCT) application has entered the European phase, or can do so, once the necessary conditions are fulfilled.

Under Articles 28, 41 PCT, Rules 52, 78 PCT and Rule 86(2) to (4) EPC, the applicant may amend the application documents after receiving the international search report.

Whether or not he has already done so, he now has a further opportunity to file amended claims or other application documents within a non-extendable time limit of one month after notification of the present communication (R. 109 EPC).

The claims applicable on expiry of the above time limit, i.e. those filed on entry into the European phase or in response to the present communication, will form the basis for the calculation of any claims fee to be paid (see page 2) and for any supplementary search to be carried out under Article 157(2) EPC (R. 109 EPC).

--2/

Registered letter

(2) Claims fees under Rule 110 EPC

If the application documents on which the European grant procedure is to be based comprise more than ten claims, a claims fee shall be payable for the eleventh and each subsequent claim within the period provided for in Rule 107(1) EPC.

☐ Based on the application documents currently on file, all necessary claims fees have already been paid (or the documents do not comprise more than 10 claims).

☑ All necessary fees will be/have been debited automatically according to the automatic debit order.

☐ The claims fees due for the claims ..... to ..... were not paid within the above-mentioned period.

Any non-paid claims fee, either based on the current set of claims or on any amended claims to be filed pursuant to Rule 109 EPC (see page 1), may still be validly paid within a non-extendable period of grace of **one month** after notification of this communication.

If a payment is made for only some of the claims, it must be indicated for which claims it is intended. If a claims fee is not paid in due time, the claim concerned is deemed to be abandoned (R. 110(4) EPC).

If claims fees have already been paid, but on expiry of the above-mentioned time limit there is a new set of claims containing fewer fee-incurring claims than previously, the claims fees in excess of those due under Rule 110(2), 2nd sentence, EPC will be refunded (R. 110(3) EPC).

You are reminded that any supplementary search under Article 157(2) EPC will relate only to the last set of claims applicable on expiry of the above time limit AND will be confined to those fee-incurring claims for which fees have been paid in due time.

The fee for the eleventh and each subsequent claim is EUR 45,00.

Receiving Section

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 1278WOORD01	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/EP2005/050334	International filing date *(day/month/year)* 27 January 2005 (27.01.2005)	Priority date *(day/month/year)* 28 January 2004 (28.01.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ALTANA PHARMA AG		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 31 July 2006 (31.07.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Agnes Wittmann-Regis e-mail: pt06@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220	**FOR FURTHER ACTION** See paragraph 2 below
International application No. PCT/EP2005/050334	International filing date *(day/month/year)* 27.01.2005
Priority date *(day/month/year)* 28.01.2004	
International Patent Classification (IPC) or both national classification and IPC A61K31/4439, A61P1/04, C07D401/12	
Applicant ALTANA PHARMA AG	

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(I) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Stroeter, T

Telephone No. +49 89 2399-8088

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/EP2005/050334

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 8-11

because:

☒ the said international application, or the said claims Nos. 8-11 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-11 (in part)

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-11
Industrial applicability (IA)	Yes:	Claims	1-7
	No:	Claims	

2. Citations and explanations

   see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 8-11 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item IV

Lack of unity of invention

The application as filed ias considered to lack unity of invention since its subject-matter relates not to one but rather to 5 separate inventions as follows:

Group 1: Claims 1-11 in part insofar as they relate to calcium salts of pantoprazole and (S)-pantoprazoles and hydrates thereof and subject-matter related to these compounds.

Group 2: Claims 1-11 in part insofar as they relate to potassium salts of pantoprazole and (S)-pantoprazoles and hydrates thereof and subject-matter related to these compounds.

Group 3: Claims 1-11 in part insofar as they relate to zinc salts of pantoprazole and (S)-pantoprazoles and hydrates thereof and subject-matter related to these compounds.

Group 4: Claims 1-11 in part insofar as they relate to lithium salts of pantoprazole and (S)-pantoprazoles and hydrates thereof and subject-matter related to these compounds.

Group 5: Claims 1-11 in part insofar as they relate to aluminium salts of pantoprazole and (S)-pantoprazoles and hydrates thereof and subject-matter related to these compounds.

These groups presented in the order chosen by the Applicant are not so linked as to form a single general inventive concept as required by Rules 13.1 and 13.2 PCT for the following reasons:

The common (structural) link between these groups of pantoprazole salts is the (S)-pantoprazole or pantoprazole component which is known (see e.g. the Mg salt disclosed in D5 or the Na salt mentioned in D1 which have the same pharmacological activity) and thus cannot constitute a special technical feature because it does not define a contribution over the prior art. Or, in other words, the structures of the compounds of these five groups have nothing more in common than each of the groups has in common with the mentioned prior art compounds.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Subject-matter of the present application

The present application discloses calcium, potassium, zinc, lithium and aluminium salts of pantoprazole and (S)-pantoprazole which are proton pump inhibitors and are thus useful in the treatment of gastrointestinal disorders.

2 Prior art documents

Reference is made to the following documents. The given numbering will be adhered to in the rest of the procedure:

D1: WO 94/24867 A (SEPRACOR INC) 10 November 1994
D2: WO 99/27917 A (BYK GULDEN LOMBERG CHEM FAB ; NEY HARTMUT (DE); DIETRICH RANGO (DE)) 10 June 1999
D3: WO 02/45686 A (BYK GULDEN LOMBERG CHEM FAB ; LINDER RUDOLF (DE); DIETRICH RANGO (DE)) 13 June 2002
D4: WO 2004/013126 A (HUMMEL ROLF-PETER ; HANAUER GUIDO (DE); KOHL BERNHARD (DE); MUELLER BE) 12 February 2004
D5: WO 00/10995 A (BYK GULDEN LOMBERG CHEM FAB ; KOHL BERNHARD (DE)) 2 March 2000

Concerning document D4 please see item VI.

3 Novelty (Article 33(2) PCT)

The presently claimed Ca-salts are a novel selection of the content of D2 (claim 5) or D3 (page 5, paragraph 3) since such compounds are not specifically disclosed as example compounds. Claims 1-11 insofar as they relate to the first invention (group 1) are novel.

4 Inventive step (Article 33(3) PCT)

It is - at present - not apparent why the presently claimed Ca-salts should be considered to form part of an inventive solution to the problem of providing alternative pantoprazol salts useful as proton pump inhibitors (PPI): Na or Mg salts of racemic or optically active pantoprazole are disclosed in D1-D3 and D5 but it is also anticipated and suggested in the relevant prior art that metals such as Ca can be used as well in order to form other pharmacologically active salts.
The present description states on page 2, last paragraph, that the present salts have unexpected and advantageous properties and refers to stability characteristics and pharmacodynamic/pharmacokinetic properties. However, this statement is not substantiated by experimental data and thus it was not yet shown that the present compounds solve the abovementioned or any other technical problem. Claims 1-11 insofar as they relate to the first invention (group 1) are therefore not inventive.

5 Industrial applicability (Article 33(4) PCT)

The subject-matter of the present claims 1-7 insofar as they relate to the first invention (group 1) is in accordance with the requirements of Article 33(4) PCT.

For the assessment of the present claims 8-11 on the question whether they are

industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI
Certain documents cited

The International Search Report mentions the P-document D4 which does not form part of the state of the art according to Rule 64.1(b) PCT. For the purposes of this communication the priorities of the present application and the above prior art have not been checked and it has been assumed that they are valid. The Applicant is informed, that D4 mentions Ca-salts of pantoprazol rendering the Ca salts of claims 1-11 not novel.

Re Item VII
Certain defects in the international application

The Applicant is informed that, when entering the regional phase at the EPO, an application may contain more than one independent claim in a particular category only certain circumstances. In the present case it appears that present claims 2-4 should be made dependent (on claim 1), as well as claim 7 (on 6) and 9-11 (on 8).

To the European Patent Office

Entry into the European phase (EPO as designated or elected Office)

European application number	EP05707853.7
PCT application number	PCT/EP2005/050334
PCT publication number	WO2005074929
Applicant's or representative's reference	1278EPPCT01
1. Applicant	
Particulars of the applicant(s) are contained in the international publication or were recorded by the International Bureau subsequent to the international publication.	☑
Changes which have not yet been recorded by the International Bureau are set out here:	☐
Address for correspondence	
2. Representative 1	
This is the representative who will be listed in the Register of European Patents and to whom notifications will be made	
Name	RIEMANN, Dr. Stephan
Address of place of business	c/o ALTANA Pharma AG P.O. Box 100310 Konstanz, 78403 Germany
Telephone	+49-(7531)-84-5171
Fax	+49-(7531)-84-5321
e-mail	DEKON.IPPA-DE@altanapharma.com
Any additional representative(s) is/are listed here:	☑ WOLF, Dr. Ulrich KRATZER, Dr. Bernd WILD, Dr. Robert MECHNICH, Dr. Oliver KRÖGER, Dr. Bernd NEELS, Dr. Solvig RUPP, Dr. Herbert
3. General Authorisation:	
An individual authorisation is attached.	☐
A general authorisation has been registered under No:	☑ 261602
A general authorisation has been filed, but not yet registered.	☐
The authorisation filed with the EPO as PCT receiving Office expressly includes the European phase.	☐
4. Request for examination	
Examination of the application under Art. 94 EPC is hereby requested. The examination fee is being (has been, will be) paid.	☑
Request for examination in an admissible non-EPO language:	☐
5. Copies	
One or more additional sets of copies of the documents cited in the supplementary	☐

European search report are hereby requested.	
Number of additional sets of copies	

6. Documents intended for proceedings before the EPO

6.1 Proceedings before the EPO as designated Office (PCT I) are to be based on the following documents:	
the application documents published by the International Bureau (with all claims, description and drawings), where applicable with amended claims under Art. 19 PCT	☑
unless replaced by the amendments attached.	☐
Where necessary, clarifications should be attached as `Other Documents`	
6.2 Proceedings before the EPO as elected Office (PCT II) are to be based on the following documents:	
the documents on which the international preliminary examination report is based, including any annexes	☐
unless replaced by the amendments attached.	☐
Where necessary, clarifications should be attached as `Other Documents`	
If the EPO as International Preliminary Examining Authority has been supplied with test reports, these may be used as the basis of proceedings before the EPO.	☐

7. Translations

Translations in one of the official languages of the EPO (English, French, German) are attached as crossed below:	☐
** In proceedings before the EPO as designated or elected Office (PCT I + II):*	
Translation of the international application (description, claims, any text in the drawings) as originally filed, of the abstract as published and of any indication under Rule 13bis.3 and 13bis.4 PCT regarding biological material	☐
Translation of the priority application(s)	☐
It is hereby declared that the international application as originally filed is a complete translation of the previous application (Rule 38(5) EPC)	☐
** In addition, in proceedings before the EPO as designated Office (PCT I):*	
Translation of amended claims and any statement under Art. 19 PCT, if the claims as amended are to form the basis for the proceedings before the EPO (see Section 6).	☐
** In addition, in proceedings before the EPO as elected office (PCT II):*	
Translation of annexes to the international preliminary examination report	☐

8. Biological material

The invention relates to and/or uses biological material deposited under Rule 28 EPC.	☐
The particulars referred to in Rule 28(1)(c) EPC (if not yet known, the depository institution and the identification reference(s)) [number, symbols, etc.] of the depositor) are given in the international publication or in the translation submitted under Section 7 on:	☐
page(s) / line(s)	
A copy of the receipt(s) of deposit issued by the depositary institution	
is attached	☐
will be filed at a later date	☐
A waiver of the right to an undertaking from the requester pursuant to Rule 28(3) EPC is attached.	☐

9. Nucleotide and amino acid sequences

The items required under Rules 5.2 and 13ter PCT and Rule 111(3) EPC have already been furnished to the EPO.	☐
The sequence listing as part of the description is attached in PDF format.	☐
The sequence listing does not include matter that goes beyond the content of the application as filed.	☐
In addition, the sequence listing data is attached in computer-readable form in accordance with WIPO Standard 25.	☐
The sequence listing data in computer-readable form in accordance with WIPO Standard 25 is identical to the sequence listing in PDF format.	☐

10. Designation fees

10.1 It is currently intended to pay seven times the amount of the designation fee. The designation fees for all the EPC contracting states designated in the international application are thereby deemed to have been paid (Art. 2 No. 3 RFees). AT BE BG CH&LI CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LT LU MC NL PL PT RO SE SI SK TR	☑
10.2 It is currently intended to pay fewer than seven designation fees for the following EPC contracting states designated in the international application:	☐
10.3 It is requested that no communication under Rules 85a(1) or 69(1) need be notified in respect of the contracting states not indicated. If an automatic debit order has been issued, the EPO is authorised, on expiry of the basic period under Article 79(2), to debit seven times the amount of the designation fee. If less than seven states are indicated, the EPO shall debit designation fees only for those states, unless it is instructed to do otherwise before expiry of the basic period.	☑

11. Extension of the European patent

This application is also considered as being a request for extension to all the non-contracting states to the EPC designated in the international application with which "extension agreements" were in force on the date of filing the international application. However, the extension only takes effect if the prescribed extension fee is paid. It is currently intended to pay the extension fee for the following states: AL BA HR MK YU LV	☑

12. List of enclosed documents

	Description of document	Original file name	Assigned file name

13. Automatic debit order ☑

Currency	EUR
The European Patent Office is hereby authorised, under the Arrangements for the automatic debiting procedure, to debit from the deposit account any fees and costs falling due.	
Deposit account number	28000022
Account holder	ALTANA Pharma AG

14. Reimbursements (if any) should be made to the following EPO deposit account: ☑

Number and account holder	ALTANA Pharma AG, 28000022

15. Fees

		Factor/Reduction applied	Fee schedule	Amount to be paid
15-1	002e Fee for supplementary European search for applications filed before 01.07.2005	0	720.00	0.00
15-2	005 Designation fee	7	80.00	560.00
15-3	006e Examination fee (Euro-PCT without supplementary European search report)	1	1 490.00	1 490.00
15-4	015 Claims fee	1	45.00	45.00
15-5	020 Basic national fee for an international application	1	95.00	95.00
15-6	403 Extension fee for Latvia	1	102.00	102.00
15-7	404 Extension fee for Albania	1	102.00	102.00
15-8	406 Extension fee for former Yugoslav Republic of Macedonia	1	102.00	102.00
15-9	407 Extension fee for Croatia	1	102.00	102.00
15-10	408 Extension fee for Bosnia and Herzegovina	1	102.00	102.00
15-11	409 Extension fee for Serbia and Montenegro	1	102.00	102.00
	Total:		**EUR**	**2 802.00**

16. Annotations

17. Signature(s) of applicant(s) or representative

Place: **Konstanz**

Date:	**27 July 2006**
Signed by:	**DE, Altana Pharma AG, S. Riemann 8661**
Capacity:	**(Representative)**

Europäisches Patentamt | European Patent Office | Office européen des brevets

Acknowledgement of receipt

We hereby acknowledge receipt of the form for entry into the European phase (EPO as designated or elected Office) as follows:

Submission number	142396	
PCT application number	PCT/EP2005/050334	
Date of receipt	27 July 2006	
Receiving Office	European Patent Office, The Hague	
Your reference	1278EPPCT01	
Applicant		
Country		
Documents submitted	package-data.xml	epf1200.pdf (4 p.)
	ep-euro-pct.xml	application-body.xml
Submitted by	DE, Altana Pharma AG, S. Riemann 8661 Subject: DE, Altana Pharma AG, S. Riemann 8661; Issuer: , European Patent Office, European Patent Office CA	
Method of submission	Online	
Date and time receipt generated	27 July 2006, 10:44:41 (CEST)	
Digest	33:9D:E4:68:66:AD:E9:94:97:22:BC:52:FB:18:B6:A3:D2:0D:47:72	

/European Patent Office/

P.B.5818 - Patentlaan 2
2280 HV Rijswijk (ZH)
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Europäisches Patentamt | European Patent Office | Office européen des brevets

Generaldirektion 1 | Directorate General 1 | Direction générale 1

WOLF, Ulrich
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ALLEMAGNE

EPO Customer Services
Tel.: +31 (0)70 340 45 00

Date
23.06.06

Reference	Application No./Patent No.
	05707853.7 - 2107 PCT/EP2005050334

Applicant/Proprietor
Altana Pharma AG

Entry into the European phase before the European Patent Office

These notes describe the procedural steps required for entry into the European phase before the European Patent Office (EPO). You are advised to read them carefully: failure to take the necessary action in time can lead to your application being deemed withdrawn.

1. The above-mentioned international patent application has been given European application No. **05707853.7**.

2. Applicants **without** a residence or their principal place of business in an EPC contracting state may themselves initiate European processing of their international applications, provided they do so before expiry of the 31st month from the priority date (see also point 6 below).

   During the European phase before the EPO as designated or elected Office, however, such applicants must be represented by a professional representative (Arts. 133(2) and 134(1), (7) EPC).

   Procedural acts performed after expiry of the 31st month by a professional representative who acted during the international phase but is not authorised to act before the EPO have no legal effect and therefore lead to loss of rights.

   Please note that a professional representative authorised to act before the EPO and who acted for the applicant during the international phase does not automatically become the representative for the European phase. Applicants are therefore strongly advised to appoint in good time any representative they wish to initiate the European phase for them; otherwise, the EPO has to send all communications direct to the applicant.

3. Applicants **with** a residence or their principal place of business in an EPC contracting state are not obliged to appoint, for the European phase before the EPO as designated or elected Office, a professional representative authorised to act before the EPO.
   However, in view of the complexity of the procedure it is recommended that they do so.

4. Applicants and professional representatives are also strongly advised to initiate the European phase using EPO Form 1200 (available free of charge from the EPO). This however is not compulsory.

5. **To enter the European phase before the EPO**, the following acts must be performed.
(N.B.: Failure validly to do so will entail loss of rights or other adverse legal consequences.)

5.1 If the EPO is acting as **designated** or **elected** Office (Arts. 22(1)(3) and 39(1) PCT respectively), applicants must, within 31 months from the date of filing or (where applicable) the earliest priority date:

a) Supply a translation of the international application into an EPO official language, if the International Bureau did not publish the application in such a language (Art. 22(1) PCT and R. 107(1)(a) EPC).
If the translation is not filed in time, the international application is deemed withdrawn before the EPO (R. 108(1) EPC).
This loss of rights is deemed not to have occurred if the translation is then filed within a two-month grace period as from notification of an EPO communication, provided a surcharge is paid at the same time (R. 108(3) EPC).

b) Pay the national basic fee (EUR 170,00) and, where a supplementary European search report has to be drawn up, the search fee (EUR 720,00 ; R. 107(1)(c) and (e) EPC).

c) If the time limit under Article 79(2) EPC expires before the 31-month time limit, pay the designation fee (EUR 80,00) for each contracting state designated (R. 107(1)(d) EPC).

d) If the time limit under Article 94(2) EPC expires before the 31-month time limit, file the written request for examination **and** pay the examination fee (EUR 1490,00 ; R. 107(1)(f) EPC).

e) Pay the third-year renewal fee (EUR 400,00) if it falls due before expiry of the 31-month time limit (R. 107(1)(g) EPC).

If the fees under (b) to (d) above are not paid in time, or the written request for examination is not filed in time, the international application is deemed withdrawn before the EPO, or the contracting-state designation(s) in question is (are) deemed withdrawn (R. 108(1) and (2) EPC). However, the fees may still be validly paid within a two-month grace period as from notification of an EPO communication, provided the necessary surcharges are paid at the same time (R. 108(3) EPC). For the renewal fee under (e) above, the grace period is **six** months from the fee's due date (Art. 86(2) EPC).

For an overview of search and examination fees, see OJ EPO 11/2005, 577 and 03/2006.

5.2 If the application documents on which the European grant procedure is to be based comprise more then ten claims, a claims fee is payable within the 31-month time limit under Rule 107(1) EPC for the eleventh and each subsequent claim (R. 110(1) EPC). The fee can however still be paid within a one-month grace period as from notification of an EPO communication pointing out the failure to pay (R. 110(2) EPC).

6. If the applicant had a representative during the application's international phase, the present notes will be sent to the representative, asking him to inform the applicant accordingly.

All subsequent communications will be sent to the applicant, or - if the EPO is informed of his appointment in time - to the applicant's European representative.

7. For more details about time limits and procedural acts before the EPO as designated and elected Office, see the EPO brochure

   How to get a European patent
   Guide for applicants - Part 2
   PCT procedure before the EPO - "Euro-PCT"

   This brochure, the list of professional representatives before the EPO, Form 1200 and details of the latest fees are now all available on the Internet under

   http://www.european-patent-office.org

Receiving section